McCarter & English

**Daniel M. Silver**
Wilmington Office Managing Partner
T. 302-984-6331
F. 302-691-1260
dsilver@mccarter.com

McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801-3717
www.mccarter.com

February 3, 2025

**VIA CM/ECF**

The Honorable Richard G. Andrews
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

**Re:** ***In re Entresto (Sacubitril/Valsartan) Patent Litigation,***
**C.A. Nos. 20-md-2930-RGA & 19-2053-RGA**

Dear Judge Andrews,

We write on behalf of Novartis and MSN regarding a recent injunction entered against MSN by the U.S. Court of Appeals for the Federal Circuit in the pending appeal regarding Novartis's '659 patent.

Specifically, on January 21, 2025, the Federal Circuit issued an order enjoining MSN "until issuance of the mandate in [CAFC Appeal No. 23-2218], from commercial marketing and sale of their generic version of Entresto®." *See* Exhibit A attached hereto, Appeal No. 23-2218, ECF No. 127. That Court also directed Novartis to file a bond in this Court in an amount and subject to terms and conditions deemed appropriate by this Court, pending issuance of its mandate directed to the '659 patent. *Id.* MSN moved on January 22, 2025, for reconsideration and *en banc* review of the Federal Circuit's injunction and asked that the injunction be stayed pending resolution of MSN's motion. Appeal No. 23-2218, ECF No. 129. The *en banc* Federal Circuit on January 28, 2025, denied MSN's request to stay the injunction but directed Novartis to respond to MSN's motion by January 30, 2025, at 5 pm EST. Appeal No. 23-2218, ECF No. 131.

Novartis is working with MSN to provide the Court with a proposed bond stipulation.

**Novartis's Position**

Novartis further writes to request a status conference to address how to proceed once the mandate issues. The Federal Circuit's injunction continues only until the mandate issues, which could happen at any time. In correspondence with counsel, MSN has stated that it will seek to launch its generic ANDA products in the "gap" after issuance of the mandate and before this Court can consider appropriate action following issuance of the mandate, including an injunction against MSN's commercial marketing and/or an order directing FDA to reset MSN's ANDA approval date under 35 U.S.C. § 271(e)(4)(A) to July 16, 2025, after pediatric exclusivity of the '659 patent expires. Such action by MSN during that gap period would deprive Novartis of its pediatric

exclusivity contrary to the Federal Circuit's entry of an injunction preserving Novartis's statutory exclusivity. This Court has jurisdiction now under Fed. R. Civ. P. 62.1 to indicate how it will rule once the mandate issues, in addition to jurisdiction under Fed. R. Civ. P. 62 and 65 to maintain an injunction both before and after the mandate issues.

Accordingly, Novartis respectfully requests a telephonic status conference with the Court on February 3 or 4, 2025 to discuss this gap period between issuance of the mandate and this Court's further orders once the case is returned after appeal. MSN's assertions that the mandate will not issue soon or may be altered are based on hypothetical scenarios that have not occurred and/or arguments that the Federal Circuit has rejected by entering an injunction against MSN. Moreover, MSN's arguments against holding a status conference with this Court now are simply an attempt to ensure that there will be a gap between issuance of the mandate and any action by this Court on remand—a gap during which MSN asserts it will launch its ANDA products. Novartis submits that a status conference is appropriate now to reduce the need for emergency action by the Court in order to properly enforce Novartis's already granted pediatric exclusivity period based on its valid patent that MSN infringed by filing its ANDA. Further, MSN's arguments focusing on its alleged entitlement to launch ignore that Novartis is simply requesting an orderly procedure for resolving the parties' disputes on the merits.

**MSN's Position**

There is no basis for granting injunctive relief and/or the advisory opinion that Novartis now seeks for the second time in a month. Novartis's request is an effort to deny MSN its rights and short cut the proper judicial process based on the faulty notions that it (a) has pediatric exclusivity that can bar an MSN launch and (b) it is entitled to immediate relief without further hearing from MSN following remand. For a host of reasons, a telephone status conference is thus not necessary or useful at this time.

**First**, nothing has changed in the law since this Court ruled that it did *not* have jurisdiction to enjoin MSN or direct FDA to re-set MSN's final ANDA approval via Rules 62, 65 or any other authority, and declined to accommodate Novartis's request for Rule 62.1 relief. Dkt. 1738. **Second**, Novartis misrepresents the record when it says the mandate could issue "at any time." MSN intends to file a rehearing petition on or before February 10. The mandate will not issue before then, and in fact will not issue at the earliest until seven days after the Federal Circuit adjudicates that petition. **Third**, no one knows what the status of this case and MSN's ability to launch will be when the mandate issues. The Federal Circuit could reverse itself following rehearing; MSN's product could be determined to have never fallen within the scope of the '659 patent (Dkt. 1722-23); and/or the patent could be delisted from the Orange Book, thereby depriving Novartis of even an argument about pediatric exclusivity (Dkt. 1728-29). Under any one of those circumstances, injunctive relief would be unquestionably inappropriate. **Fourth**, Novartis is wrong to suggest it would *ever* be awarded an injunction because MSN does not agree it is entitled to

pediatric exclusivity, and the Federal Circuit has *never* indicated it took action to "preserve Novartis's statutory exclusivity . . . ."

Once the mandate issues, Novartis may approach this Court then. This letter is just Novartis's most recent maneuver in its ceaseless campaign to deny U.S. patients the benefits of generic Entresto® even after the '659 patent expired. In fact, just last Friday at 4:08 a.m., Novartis filed a temporary-restraining order/preliminary-injunction motion in the District Court of New Jersey seeking to block MSN *again* from selling its generic Entresto® product. That action is in addition to other pending actions involving FDA in both the D.C. District Court and Circuit Court. Every court except the Federal Circuit has now denied Novartis's requests for injunctive relief, and its arguments should fare no better in this Court where Novartis is asking for some form of preemptive advisory relief based on unknown hypothetical facts ahead.

Respectfully submitted,

*/s/ Daniel M. Silver*

Daniel M. Silver (#4758)

cc: Counsel of Record (via Electronic Mail)